K102756

NOV 2 9 2011

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name, Address, Phone and Fax Number of Applicant

Chest Innovations, Inc.
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San Jose, CA 95136
Phone: (408) 826-9740
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B. Contact Person

Salmaan Hameed
Chief Executive Officer
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Regulatory Affairs Consultant
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C. Date Prepared

November 28, 2011

D. Device Name

Trade Name:	SureCore™ Biopsy Device
Common Name:	Biopsy Instrument
Classification Name:	Biopsy Instrument (21 CFR§ 876.1075, Product Code KNW) and Electrosurgical, Cutting & Coagulation & Accessories (21 CFR§878.4400, Product Code GEI)

E. Predicate Devices

The SureCore™ Biopsy Device is substantially equivalent to:

K102756

- Neothermia Corporation en-bloc® Biopsy System K050737 cleared March 31, 2005
- Angiotech BioPince™ Ultra Full Core Biopsy Instrument K101832 cleared August 27, 2010

F. Device Description

The SureCore™ Biopsy Device is an electrosurgical breast tissue biopsy device that is shipped sterile and intended for single use.

G. Intended Use

The Chest Innovations' SureCore™ Biopsy Device is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. The instrument is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

H. Technological Comparison

Manufacturer	Chest Innovations	Neothermia Corporation	Angiotech
Device Name	SureCore™ Biopsy Device	en-bloc ®Biopsy	BioPince™ Ultra Full Core Biopsy Instrument
510(k) Number	K102756	K050737	K101832
Intended Use	provide tissue samples for diagnostic sampling of breast abnormalities.	provide tissue samples for diagnostic sampling of breast abnormalities.	multiple percutaneous full-core sampling of soft tissue, tumors, or masses for histological analysis. Soft tissue sampling includes, but is not limited to, kidney, liver, breast, prostate and various soft tissue lesions.
Product Code	KNW; GEI	GEI	KNW
Mechanism of Action	radiofrequency energy to cut the tissue during open surgical or endoscopic procedures	radiofrequency energy to cut the tissue during open surgical or image guided procedures	mechanical cutter to cut the tissue during percutaneous, open surgical or endoscopic procedures

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Sample Size	Cylindrical, full core specimen 2.4 mm Diameter x 10-20 mm	Cylindrical, full core specimen 10mm wand: 12mm x13mm 12mm wand 13mm x 17mm 15mm wand: 14mm x 18mm 20mm wand:18 mm x 18 mm	Cylindrical, full core specimen 1.3mm-1.6mm Diameter. The 13mm stroke length yields a specimen of 9mm length, the 23mm stroke length yields a specimen of 19mm length, and the 33mm yields a specimen of 29mm length.
Average Tissue Volume	37.9 mm^3 (2.4mm with 10mm stroke length)	1470.9mm^3 (10mm wand)[1] 2257.4mm^3 (12 mm wand) 2772.0mm^3 (15 mm wand) 4582.3mm^3 (20 mm wand)	16.5 mm^3 (1.6mm diameter device with 13mm stroke length)
Profile	10.5G 24 cm long	5.3 mm Shaft Diameter 11.6 cm long	14G, 16G, 18G and 20G needle sizes 10cm, 15cm and 20cm lengths
Energy Type	RF Valley Lab Force II Generator	Proprietary Generator, NeoThermia™ Model 3000	Mechanical, spring mechanism for firing of needle.
Power	Standard 120 V	Standard 120 V	N/A
Electrical Energy Delivered	Monopolar Radio Frequency 510 kHz Sinusoidal wave, Max 65 Watts	Monopolar Radio Frequency 350 kHz Sinusoidal wave, Max 250 watts	N/A

I. Summary of Non-Clinical Data

SureCore™ Biopsy Device performance characteristics were evaluated in the following non-clinical studies: device tensile strength, *in-vitro* device performance, electrical safety, electromagnetic compatibility, electrical safety for endoscopic equipment, sterility testing, shelf life testing, biocompatibility and *in-vivo* animal device performance.

Results of the pre-clinical testing demonstrate that the materials chosen, the manufacturing process, and design of the SureCore™ Biopsy Device meet the established specifications necessary for consistent performance during its intended use. In addition, the testing demonstrates the SureCore™ Biopsy Device is substantially equivalent to the named predicates.

J. Summary of Data

The SureCore™ Biopsy Device has been carefully compared to a legally marketed device with respect to intended use and technological characteristics. In addition, non-clinical testing was conducted to validate the performance of the device and ensure the SureCore™ Biopsy Device performs as intended and meets the design specifications. The non-clinical performance testing and comparison to the predicate device demonstrate that the SureCore™ Biopsy Device is substantially equivalent to the predicate device and does not raise new issues of safety or effectiveness.

[1] *Intact*™Specimen Capture Volumes©2005 Intact Medical Corporation. ML082, Rev. 0

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 2 9 2011

Chest Innovations, Inc.
% Mr. Salmaan Hameed
Chief Executive Officer
827 Canoas Creek Circle
San Jose, California 95136

Re: K102756
Trade/Device Name: SureCore™ Biopsy Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, KNW
Dated: November 11, 2011
Received: November 14, 2011

Dear Mr. Hameed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102756

Device Name: Chest Innovations, Inc. SureCore™ Biopsy Device

INDICATIONS FOR USE

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Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102756